

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

5 In re Application of: Huynh, et al.) Group Art Unit: 3738
Application No.: 10/802,314) Examiner: Brian E. Pellegrino
Filing Date: March 17, 2004) Confirmation No.: 3894
10 For: LOW-PROFILE HEART VALVE SEWING RING) **Customer Number: 30452**
AND METHOD OF USE)

Mail Stop APPEAL
15 Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY BRIEF UNDER 37 C.F.R. §41.41

20 Dear Sir:

This is an appeal from the final rejections of claims 1-21 in the FINAL Office Action dated March 20, 2008. The Appeal Brief was timely filed on September 22, 2008.

This is responsive to the Examiner's Answer dated October 5, 2010.

25 It appears that Examiner Pellegrino has modified the ground of rejection, but notation of such has not been officially provided. Specifically, the following are the grounds of rejection provided in accordance with 37 CFR §41.37(vi) in the Appeal Brief:

1. Whether claims 1-8 and 11-19 are not patentable under 35 U.S.C §102(b) as being anticipated by Totten, et al. (USPN 4,477,930, hereinafter, "Totten").
- 30 2. Whether claims 1-7 and 11-19 are not patentable under 35 U.S.C §102(b) as being anticipated by Vanney, et al. (USPN 5,843,179, hereinafter, "Vanney").
3. Whether claims 9 and 20 are not patentable under 35 U.S.C §103(a) as being obvious over Totten in view of Huynh, et al. (USPN 5,928,281, hereinafter, "Huynh").
4. Whether claims 10 and 21 are not patentable under 35 U.S.C §103(a) as being obvious
35 over Totten in view of Reichart, et al. (USPN 4,626,255, hereinafter, "Reichart").

The following lists the grounds of rejection specifically enumerated in the Examiner's Answer:

- 40 1. Whether claims 1-8 and 11-19 are not patentable under 35 U.S.C §102(b) as being anticipated by Totten, et al. (USPN 4,477,930, hereinafter, "Totten").

2. Whether claims 9 and 20 are not patentable under 35 U.S.C §103(a) as being obvious over Totten in view of Huynh, et al. (USPN 5,928,281, hereinafter, "Huynh").
3. Whether claims 10 and 21 are not patentable under 35 U.S.C §103(a) as being obvious over Totten in view of Reichart, et al. (USPN 4,626,255, hereinafter, "Reichart").

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In other words, there is no more mention of rejection 2) based on Vanney, et al., and therefore Appellants assume that the Examiner no longer relies on such rejection. However, in the Examiner's Answer, item (6), he states that every ground of rejection set forth in the Final Office Action is being maintained unless listed under the subheading "WITHDRAWN REJECTIONS," and there is no such subheading. Therefore, Appellants request clarification - is the rejection based on Vanney still applicable?

In any event, the following remarks are in reply to the Examiner Pellegrino's statements beginning on page 5 of his Answer.

15 The Examiner begins by asserting that "Appellant never explains in the argument how the feature at issue of the sewing ring being bi-stable is defined or established." This sounds like a new contention. Previously, the Examiner has appeared to understand the characteristic of the sewing ring being bi-stable. See, for example, the Final Office Action dated March 20, 2008, page 4, lines 7-9, where Examiner Pellegrino asserts that Totten's sewing ring is "clearly capable of pivoting between two positions and would be stable in the first or second positions the sewing (sic) can be considered bi-stable." If the Examiner understands what bi-stable means, then Appellants fail to see how the claims can be interpreted more broadly so as to be anticipated by a merely flexible ring such as in Totten.

20 Examiner Pellegrino then contends that a claim can be incomplete for omitting essential elements that provide the support for the functional language to occur, citing MPEP §2172.01. As a result of this "omission," the Examiner eviscerates the claims to instead specify a sewing ring that simply moves between two positions, *ergo*, the sewing ring in Totten can be flexed between two positions and anticipates the claims. The crux of the Examiner's argument is that claims 1 and 11 omit "essential elements that provide the support for the functional language to

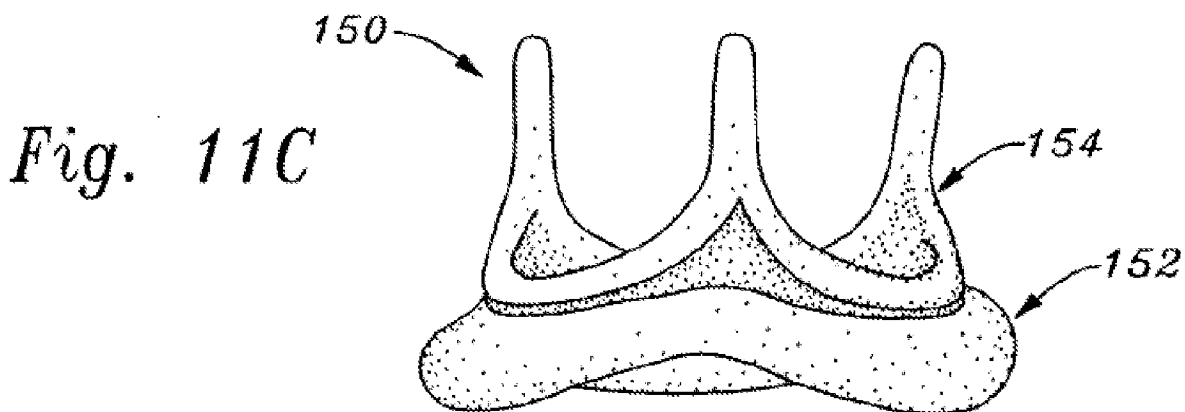
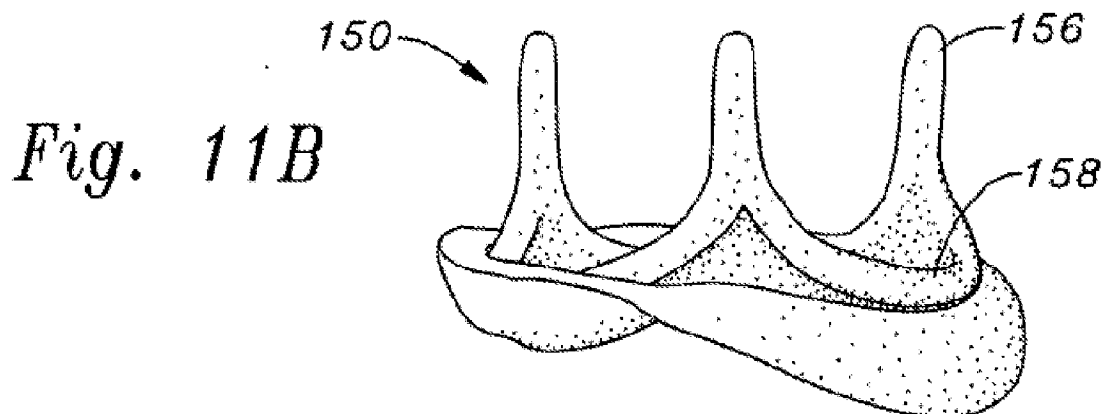
occur.” However, a quick read of MPEP §2172.01 shows only that there is case law supporting rejections under 35 USC section 112, first and second paragraphs, for certain claim omissions. There is nothing in the MPEP section that supports the Examiner's logic that because of an alleged omission the claim is read more broadly than is clear from the specification, and from the Examiner's own understanding. The following are passages from the specification regarding the capability of the sewing ring to pivot (claim 1) or move (claim 11) between two bi-stable positions:

[0032] FIGS. 11A-11C are elevational views of a stent/sewing ring subassembly of an exemplary aortic or pulmonic heart valve of the present invention illustrating conversion of the sewing ring between two bi-stable positions;

[0034] FIGS. 13A and 13B are cross-sectional views through the stent/sewing ring subassembly of FIGS. 11A-11C illustrating in more detail the sewing ring in the bi-stable positions;

[0071] Because of the novel connection between the sewing ring 152 and stent 154, the two positions shown in FIGS. 11A/13A and 11C/13B are bi-stable. Specifically, the band 172 of the insert 160 creates a generally frustoconical sewing ring 152 that can be inverted between orientations extending toward the outflow end and the inflow end. The resiliency of the insert 160 means that the outer circular edge 164 is stretched and placed in tension as it passes between the two positions, thus biasing the insert one way or the other. This bi-stable configuration greatly assists during both the manufacturing process, and the implantation procedure, as mentioned above. During manufacture, the fabric-covered stent/sewing ring subassembly 150 is constructed, and the tissue leaflets 196 and wireform assembly 198 are added. Because the sewing ring 152 can be pivoted away from the stent 154, attaching the leaflets 196 and wireform assembly 198 is simplified. That is, the suturing needle can more easily be passed through the various components to form the stitch line 230 when the sewing ring 154 is displaced out of the way. Various fixtures may be used during the assembly process as was described above with respect to the first embodiment.

It is clear from these passages, and from the figures, in particular Figures 11B and 11C which are reprinted below, what bi-stable means:



Appellants assert, therefore, that a) the claim terms are sufficiently clear and complete as to provide essential elements, and b) in any event the Examiner has not made any section 112
5 rejections.

Appellants also wish to note that the Examiner has misquoted from our Appeal Brief. The Examiner quotes from page 4 of the Brief submitted on 9/22/08 “that bi-stable means an element is movable between two positions.” This is a central point of his argument as it allows him to conflate the flexible sewing ring of Totten with the sewing ring as claimed in the present

application. However, as has been stated elsewhere in the prosecution, and was stated in the Appeal Brief on page 4, "bi-stable means that the element moves between two **stable** positions." (Emphasis added) In general terms, a bi-stable device has two stable positions. For example, a light switch. We are not claiming a sewing ring that merely moves between two positions, but
5 instead a sewing ring that moves between two bi-stable positions. There is a big difference.

Next, on page 6 of the Examiner's Answer, Examiner Pellegrino asserts: "that the term 'stable' is a word that describes a condition of an element, but without any comparative measures it has no special meaning. This term has many meanings, i.e. 1) not subject to change 2) does not deteriorate. In considering these general or common definitions it clearly can be said that the
10 pliability of Totten's sewing ring allows for the ring to move without deforming or changing permanently since it is flexible. Additionally since the ring is not made of the degradable material clue does not deteriorate."

These points raised by the Examiner avoid the issue. The specification clearly describe and shows what is a bi-stable sewing ring. We have repeatedly explained this to the Examiner
15 during this lengthy prosecution, and this muddying of the waters by claiming not to understand what "stable" means, let alone "bi-stable," is beside the point. Once again, the claim language is clear and supported by the specification, and the prior art does not disclose a bi-stable heart valve sewing ring.

Examiner Pellegrino's ultimate conclusion, at the bottom of page 6, is that since Totten's
20 "ring moves or pivots the sewing ring can be said to go from one position to another and maintains a stable condition since it will not change or even deteriorate. As a result it can be said that Totten's sewing ring then has two bi-stable positions." Appellants reiterate that a flexible sewing ring such as disclosed in Totten certainly can be deformed into various positions, but those positions are not all stable. A flexible sewing ring of the prior art has a single stable
25 position, it is not bi-stable.

Indeed, Examiner Pellegrino understands and explicitly acknowledges that the sewing ring in Totten does not move between two bi-stable positions when he responds to Appellant's complaint that he is not giving sufficient weight to the claim terms. From the bottom of page 6: "the Examiner has merely explained that the sewing ring moves between two positions, but since

the claims and specification fail to establish what defines a 'stable' position, the broadest interpretation is given to the terms." Therefore, Appellants contend that if the Appeal Board finds the claim terms are clear and enabling as to "bi-stable," then they must be patentable because the Examiner does not allege that Totten discloses a [well-understood] bi-stable sewing
5 ring.

On page 7 of his Answer, the Examiner delves even further into the central argument when he cites page 16 of the specification where "the two positions define 'bi-stability'. So since such a structure is described to just have the ability to move between two positions, it is bi-stable." (underlining added) Appellants note the passages quoted above from the specification,
10 and the drawings. Specifically, in paragraph [0071], the "resiliency of the insert 160 means that the outer circular edge 164 is stretched and placed in tension as it passes between the two positions, thus biasing the insert one way or the other. This bi-stable configuration greatly assists during both the manufacturing process, and the implantation procedure, as mentioned above." Given this evidence, Appellants fail to see how the Examiner ends up with a definition of bi-
15 stability which is as broad as something that merely moves or pivots between two positions. Furthermore, we do not see that Totten's sewing ring can pivot between two positions, as we have previously explained at great length.

Appellants find nothing remarkable or novel in the Examiner's comments with regard to the obviousness rejections that is worth rebutting.

Respectfully submitted,

Date: December 6, 2010

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